UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/Counter-Defendant,

v.

INTUITIVE SURGICAL, INC.,

Defendant/Counterclaimant.

Case No. 3:21-cv-03496-VC

Honorable Vince Chhabria

EXPERT REPORT OF JEAN SARGENT

Complaint Filed: May 10, 2021

Highly Confidential – Subject to Protective Order

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I. QUALIFICATIONS

1. I am President at Sargent Healthcare Strategies, a consultancy that supports patient safety and cost-effective healthcare delivery at hospitals and healthcare facilities.

2. I attended the University of New Mexico for undergraduate studies, Cypress College where I received my Associates of Science in Business, and I am currently attending California Coast University to complete my Bachelor of Science in Healthcare Management.

3. I have received accolades and awards as a result of my work in the healthcare supply chain management and processing fields, as outlined in Attachment 1.

4. I have been a member of the International Association of Healthcare Materials Management (IAHCMM), now Healthcare Sterile Processing Association (HSPA), since 1992. Through that organization, I received my Central Service Registered Certified Technician (CSRCT) in 1992, Certified Central Service Management Concepts (CCSMC) in 1993, Central Service Fellow in 1997, and Approved Certified Educator (ACE) in 1998. In addition, I was chair of the Fellowship Committee in 1998-1999 and Professional Development Resource Committee (PDRC) in 2000-2004. I received the Past President's Award in 1997 for my contributions to the national and local (California) IAHCMM organizations. As chair of the PDRC, I worked with other ACEs to develop education, including speakers, articles and publications, for the membership. I participated in updating the 7th Edition of the Central Service Technicians Course, which was a full revision of the 6th Edition. I was a writer and editor for the 8th Edition, as well as for a complete re-write of the Certified Healthcare Leader text, formerly the CCSMC. I taught the CRCST course to over 200 students in 2001-2006.

5. I joined the national and local chapter of Association Healthcare Resource and Materials Management (AHRMM) in 1996. I was president of the local/state chapter for Southern California of AHRMM from 1998-2002.

6. I have continued my involvement with both the IAHCSMM/HSPA and AHRMM organizations to this day. With AHRMM I was a member of the education committee from 1999-2004, Fellowship Committee from 2015-2020, Region 9 representative from 2002-2005, President-elect in 2006, President for 2007, and past-president for 2008. In 2010 I received the Louis Gossett, Jr. Award for my contributions to the organization.

7. With AHRMM, I received my Certified Senior certification in 1997, Certified Materials Resource Professional (CMRP) certification in 2004, Fellowship in 2006, and Lifetime Fellow in 2019. In 2009, I led a group of subject matter experts in updating the text for the Managing Hospitals Materials Management portion of the Healthcare Supply Chain Management: Resource and Logistics Processes Manual.

8. In 2019, I co-authored an update to the AHRMM Policy and Procedure Manual. I led and participated in AHRMM's Unique Device Identifier (UDI) Learning Community to develop processes by which healthcare would adopt the UDI.

9. I began my career in healthcare sterile processing and materials management in 1976. I worked my way into leadership roles beginning in 1989 at Downey Community Hospital in Downey, California. In 1997, I started working at the University of California Los Angeles (UCLA) healthcare system, as the Director of Central Service and Receiving. In this role, I reported to the Chief Financial Officer (CFO) with responsibilities for the management of the Central Service and Receiving functions within the UCLA system, including two hospital departments and a medical office complex. These responsibilities included management of inventory procurement, distribution and management including point of use inventory management system, equipment purchases and tracking, exploring and implementing efficiencies and process improvements, sterilization, decontamination, receiving, mail room, data processing,

and training of staff. I participated in the design of two new hospitals. In this role, I directed 120 employees including seven managers, had an operating budget of $12.2M, and revenues of $73M.

10. I joined the University of Kentucky healthcare system in 2007 as Director of Supply Chain. In this role, I reported to the Senior Vice President for Health Affairs and Chief Financial Officer (CFO) with responsibilities for supply chain management including purchasing, warehouse, receiving, supply distribution and equipment management, and linen distribution functions within a health network comprised of an academic medical center, a community hospital and a warehouse. I directed 90 employees, had an operating budget of $23M, and managed an inventory of over $12M. My responsibilities at UK included inventory procurement, distribution and management to include an automated point of use inventory management system, equipment purchases and tracking, implementation of efficiencies and process improvements/LEAN, receiving, training of staff, consultation with decontamination, sterile processing, infection control, and environment of care. I participated in the design of a replacement hospital within the system. While I was there, UK had purchased an Intuitive robot that sat in a storage room and was allowed to be used on prostate procedures only, due to the excessive cost per use. At the time of my departure in 2012, no other procedures were approved for use due to the cost.

11. In 2009, I returned to California to a role as Director of Supply Chain at the University of Southern California (USC) healthcare system. At USC I reported to the Associate Vice President Business Services for USC and Chief Financial Officer for Keck Medical Center of USC with responsibility for purchasing for USC medical schools and research, healthcare materials supply chain management, capital purchasing, and value analysis and contracting within the hospitals and medical office sites. I also served as liaison to Sterile Processing, Infection Prevention, and Compliance committees within the USC medical center. Around 2011, USC

owned an Intuitive da Vinci robot and the surgeons were asking for another. However, there was no funding for a second da Vinci robot. Nevertheless, an Intuitive sales representative spoke with a physician who requested that Intuitive ship a new robot, without either Intuitive or the physician obtaining approval from the hospital system. The da Vinci robot arrived at the dock early on a Monday morning and was being off-loaded when I arrived. Intuitive, however, would not take the da Vinci robot back, as they considered it to be USC property on delivery. As a result of the impasse, the da Vinci robot sat in a back hallway of the medical center for four months while senior leadership worked to resolve the conundrum. The da Vinci robot was eventually paid for and was placed in service.

12. I joined MedAssets as a Director in 2012. At that time, MedAssets was one of the largest medical performance improvement companies in the country. It is a Group Purchasing Organization ("GPO") and has since merged with VHA to become Vizient, the country's largest GPO. As a Director at MedAssets, I functioned as a Project Lead for a large county Integrated Delivery Network ("IDN") ensuring cost savings analyses were performed, appropriate stakeholders were involved and contracting was completed, and monitoring implementation of contract/cost savings and tracking of cost savings. I served as a liaison between the IDN Chief Financial Officer, Vice President of Supply Chain, and Project Management Office on the one hand, and MedAssets on the other hand. I led project management of various standardization, utilization, and contract compliance efforts to include data management, strategic vision, and presentations to key stakeholders. I was a member of the content development group and instructors for MedAssets' Supply Chain University, which is a three-day class reviewing aspects of supply chain management including value analysis, procurement, contracting, hospital

administration. I also performed process mapping for supply chain and purchased services categories, and performed supply chain assessment including support services categories.

13. I joined USDM Life Sciences in 2015 as Vice President of Healthcare Implementation. My primary duties were to engage with healthcare/hospitals senior supply chain leaders to offer assistance in implementing Food and Drug Administration (FDA) guidelines for the Unique Device Identifier (UDI).

14. As mentioned above, I am currently President at Sargent Healthcare Strategies. Sargent Healthcare Strategies is a consultancy that supports patient safety and cost-effective healthcare delivery at hospitals and healthcare facilities via supply chain management, sterile processing and operating room processing, interim department and personnel management, strategic planning, assessment and strategy development, systems implementation, and education. As an independent consultant, I have been exposed to the inner workings and administration of many hospitals.

15. While working as a consultant with Marin Health (then known as Marin General Hospital) in 2019 on cost saving efforts, I was informed of an EndoWrist repair program being offered by Surgical Instrument Service Company, Inc. ("SIS"). Believing that the SIS program might benefit Marin Health by significantly reducing its EndoWrist costs, I shared information about the EndoWrist program with Marin Health staff. Marin Health proceeded to work with SIS for its EndoWrist repair program, and both the operating staff and hospital leadership were excited about the anticipated cost savings. The cost savings, however, never materialized because Intuitive sent a cease and desist letter to Marin Health shortly after it began using the program with SIS, and the program was discontinued in response to that letter. I had an opportunity to

view the letter at the time, and am confident that the letter having bates label SIS000202 is the same letter.

II. PRIOR TESTIMONY AND PUBLICATIONS

16. I have been an expert in one case in the past, in which I was hired by the law firm of Womble, Carlyle, Sandridge and Rice to represent Duke University. This case was in 2000s, and I prepared an expert report and was deposed. Other than this matter, I have not served as an expert in a litigation matter.

17. A list of all publications I have authored or co-authored during the past ten years is included in Attachment 1.

III. ENGAGEMENT AND COMPENSATION

18. I am submitting this Report at the request of Haley Guiliano LLP, counsel for Surgical Instrument Service Company, Inc. ("SIS"), the named plaintiff in the lawsuit captioned on this Report's first page. This Report sets forth opinions I have formed about which I may testify if called as a witness at the trial of this action.

19. I am an independent expert with extensive experience in hospital processing and procurement processes for instruments used in surgical procedures. I have been asked to provide opinions about procurement of instrument repair services from GPOs and hospital practices regarding Food and Drug Administration ("FDA") approvals and clearances for instrument repair services.

20. In addition to my personal experiences, the facts, data, and documents I considered in connection with forming my opinions are identified in the body of this report and at the attached Attachment 2.

21. I am being compensated for my time spent in preparing this Report at an hourly rate of $500. If asked to testify in this lawsuit, I will be compensated at the hourly rate of $500 for deposition testimony and for testifying at trial. My compensation does not depend in any way on the outcome of this action.

IV. SUMMARY OF OPINIONS

22. Except in rare circumstances, hospitals do not consider whether FDA device approvals and clearances such as 510(k) have been obtained for servicing and repair services of instruments that are owned by the hospital. Hospitals repair numerous types of devices and instruments of varying complexity, and typically contract with third-party independent service organizations ("ISOs") to outsource this function. So long as the hospital-owned device functions properly when returned, from the hospital's perspective the device is suitable for further use.

23. Where equivalent services are offered to a hospital from a service provider approved by a GPO versus a service provider not approved by the GPO, the hospital will almost always default to using the GPO-approved supplier. GPOs such as Vizient have rigorous review processes for selecting suppliers such as ISOs and negotiating agreements with those suppliers. Hospitals rely on GPOs to perform this screening function, and there are substantial administrative benefits to using a GPO-approved supplier.

V. HOSPITALS ARE NOT CONCERNED ABOUT FDA APPROVALS AND CLEARANCES FOR INSTRUMENT SERVICING AND REPAIR OF HOSPITAL OWNED INSTRUMENTS

24. The hospital department responsible for cleaning, disinfection, and sterilization of instrumentation between surgeries is generally referred to as the Sterile Processing Department ("SPD"). The SPD is responsible for understanding how to take apart various types of devices and instruments, how to appropriately clean and disinfect, reassemble, test for use, and sterilize the

devices and instruments, including using the correct method, equipment, chemicals, time, and temperature.

25. The SPD staff is trained on basic functionality testing for certain instruments/devices between surgeries. An instrument or device that is tested and does not meet the hospital-internal testing standard is sent to a third-party repair vendor such as an ISO like SIS. Many instruments or devices are too complicated for internal hospital repair, and/or the department does not have the tools or knowledge for testing and repairing of the instruments or devices. These instruments and devices are sent to a third-party repair vendor who has the tools, expertise and experience for testing and repairing the devices.

26. The types of instruments and devices handled by SPD for sterile processing range in complexity from forceps, to scissors/hemostats, to DaVinci EndoWrist instruments, to rigid and flexible endoscopes, and to powered electronic medical devices. Each device has its own Instructions for Use ("IFUs") that incorporate procedures for processing between surgeries, and in some instances, functional testing. Again, not all devices are testable in the SPD, and the SPD depends on hospital personnel (such as operating room staff and surgeons) to notify the SPD of a device that is not functioning properly. In either event, if functional testing in the SPD or hospital personnel identify an instrument that is not functioning properly, and if we believe that the instrument may be repairable, the instrument is then sent to a third-party service for repair and subsequent return to the hospital.

27. I understand that the FDA requires manufacturers to provide IFUs for devices and instruments. An IFU details the type of cleaning solution/dilution, time to soak, rinsing instructions, and type of mechanical cleaning equipment that can be used to complete the disinfection process of a particular medical instrument. Mechanical cleaning equipment includes

such things as ultrasonic washers, washer disinfectors, and scope cleaners. The mechanical cleaning equipment will have standard cycles programmed by type of device or instrument, including: general, orthopedic, spine, eye, neuro, etc. Each type of device will have a set time on the equipment for washing, rinsing, and drying. Should the incorrect cycle be utilized, the device or instrument being processed may become damaged. It is important, therefore, that each SPD technician be aware of the proper cleaning, disinfecting, drying, and mechanical equipment that is safe and effective for use with each device.

28. An IFU may also provide instructions for testing or inspection between surgical uses. As an example, Intuitive's "Instruments and Accessories User Manual"[1] for S and Si EndoWrists includes Section 2 that provides "general information that applies to all EndoWrist Instruments."[2] Section 2.2 includes "Instructions for Use" including "Inspection Before Use" and "Intraoperative Use."[3] Hospital staff that process and prep EndoWrist instruments between surgeries must be cognizant and familiar with the instrument's "Inspection Before Use" which instructs as follows:

2.2 Instructions for Use

Inspection Before Use

Before use, all instruments should be inspected for damage or irregularities. Do not use the instrument if damage or abnormalities are observed. Examples of damage include: broken cables, broken wires, scratches or cracks on the instrument shaft, broken, bent, or gouged instrument tips, cracked or broken pulleys near the instrument tips, cracks or missing pieces on the outer components surrounding the pulleys, loose tip or grips, or broken lever guards (if applicable).

⚠ **CAUTION: Endoscopic instruments are designed and manufactured for a specific surgical function. Use of an instrument for a task other than the instrument's designed use may result in a damaged or broken instrument.**

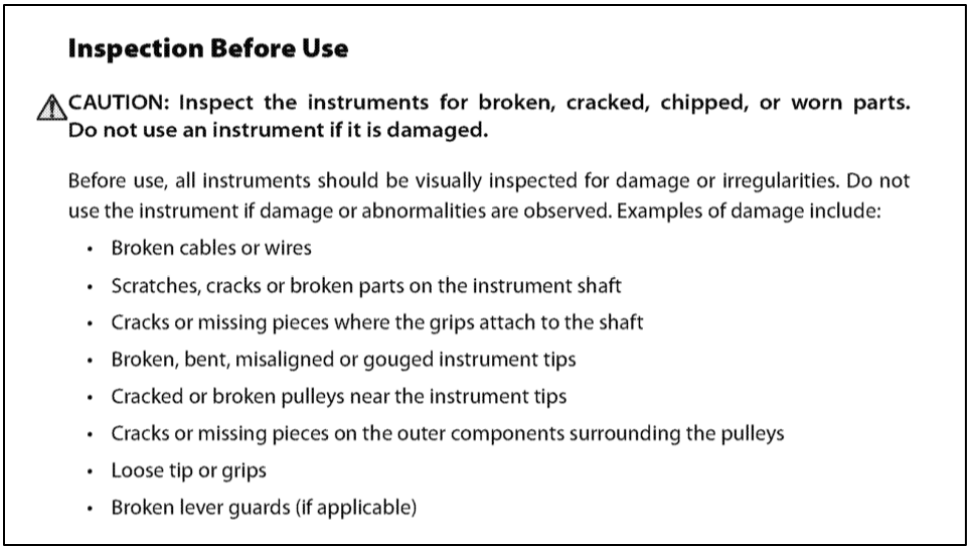
[1] Intuitive-00000501
[2] Intuitive-00000501, at 510.
[3] Intuitive-00000501, at 518

29. This sort of generalized inspection, which checks for visible or obvious functional errors or failures, is typical of the sort of testing that hospital staff perform for instruments used in surgery. In the instance such an inspection raises concerns, the typical process would be to set the instrument aside and have a third-party such as an ISO investigate further and, if possible, repair the instrument.

30. IFUs also include disinfection/sterilization instructions. After disinfection is complete, the devices are sent to a clean area to be tested and assembled into trays defined by a set list of instruments. As a tech is assembling the instrument set, they will typically perform a generalized testing and inspection similar to that described above for the Intuitive Si instruments, such as testing scissors for cutting, forceps and hemostats for clamping, lumened instruments for debris, and the like. For an EndoWrist, the departments I was in would follow the process noted in the Intuitive reprocessing IFUs.[4]

31. Intuitive Xi instrument manuals[5] provide "Inspection Before Use"[6] IFUs similar to those for Si EndoWrists discussed above:

[4] da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, PN 554324-01 Rev. B
[5] Intuitive-00284844
[6] Intuitive-00284844, at 858



Inspection Before Use

⚠ **CAUTION: Inspect the instruments for broken, cracked, chipped, or worn parts. Do not use an instrument if it is damaged.**

Before use, all instruments should be visually inspected for damage or irregularities. Do not use the instrument if damage or abnormalities are observed. Examples of damage include:

- Broken cables or wires
- Scratches, cracks or broken parts on the instrument shaft
- Cracks or missing pieces where the grips attach to the shaft
- Broken, bent, misaligned or gouged instrument tips
- Cracked or broken pulleys near the instrument tips
- Cracks or missing pieces on the outer components surrounding the pulleys
- Loose tip or grips
- Broken lever guards (if applicable)

32. Instrument repair is critical to patient care, lowering costs, and maintaining proper functionality of medical devices. Improperly maintained medical devices can impact the ability of physicians and clinicians in operating rooms and other procedural areas to quickly and efficiently take care of the patients, resulting in extended hospital stays and, in worst cases, patient harm. Reusing surgical instruments that still function properly, and repairing those that are capable of being returned to proper use, provides substantial savings to hospitals that directly impact (by substantially reducing) the cost of care and ability to hire and retain staff. Instrument costs are a substantial and ever-growing part of hospital budgets and the spiraling cost of health care, and reducing those costs where it can be done without sacrificing patient safety is critical to hospital operations.

33. These repair and maintenance functions are typically provided by ISOs, who specialize in the collection, testing and repair of instruments and who provide services at substantial cost savings as compared to providing the same services by hospital staff or the OEM. Accordingly, it is standard operating procedure for hospitals to outsource their in-depth testing, maintenance, and repair needs to ISOs who specialize, and have years of experience, in providing such services. ISOs thus are an important aspect of how hospitals provide the high quality

healthcare that they do. The testing and repair services provided by ISOs are important to and directly impact patient care and safety, staff satisfaction, and budget control. ISO services provided to hospitals, and the experience ISOs bring in providing those services, would be difficult if not impossible for hospitals to provide or match, in terms of ISO levels of quality, expertise, and cost, from an in-house service department.

34. Group Purchasing Organizations (GPOs) are described in more detail later in my report. In general, these organizations perform a contracting function on behalf of a large group of hospitals, helping achieve cost reductions and lowering hospitals' administrative burdens. Services that are procured via GPOs include ISO services.

35. Hospitals rely on ISOs and GPOs to ensure FDA regulatory compliance by manufacturers and vendors. Hospitals do not have the time, staff, nor expertise to maintain a database or analyze and track the hundreds of manufacturers and vendors that provide services and devices to the hospitals.

36. Hospital purchase of services, devices, and instruments is the responsibility of a purchasing/procurement group within supply chain function for the hospital. Prior to making purchases, it is left to sourcing/contracting personnel within supply chain to ensure that purchased services, devices, and/or instruments comply with hospital contracting practices, such as allocation of liability and other legal terms and conditions. One of the reasons that hospitals prefer to work with GPOs is that they can rely on the GPOs for these contract negotiation functions, reducing the need to create local agreements specific to the hospital and its many and varied vendors and manufacturers. Without the GPO's contracting services, a hospital would have to put a local agreement into place, which can be a substantial administrative and legal burden and require retaining costly outside counsel to assist in drafting the contract.

37. The ISO that a hospital contracts with is expected to repair all hospital-owned devices within the scope of the contract that are capable of being repaired to their proper functionality. It is up to the ISO to provide the expected repair service or, if the device is beyond safe repair, to notify the hospital so that the hospital can purchase a new instrument. Hospitals do not want an ISO to return to the hospital devices that are not fully and properly repaired, such that the device does not function properly, safely, or reliably. A device returned by an ISO that is not properly operational can endanger staff and patients, and thus be a liability issue for both the hospital and ISO.

38. I am aware that most OEMs push for new instrument sales or to perform repair service themselves, rather than have such services performed by less expensive ISOs. Unless the OEM has some other form of leverage, there is actual evidence that an ISO-repaired hospital-owned instrument was improperly serviced, or the particular ISO in general is providing poor service, a hospital will typically stick with an ISO partner despite OEM sales pitches about inferiority of ISO services or purported regulatory issues.

39. In my years of experience, I have not heard of any provider of repair services of hospital-owned instruments having to obtain FDA approval, such as by way of 510(k) clearance, to provide its repair services. Nor, in my experience, do hospitals in retaining ISO repair services typically inquire about the need of FDA clearance for those services. In any event, hospitals rely upon the ISO and the GPO to vet regulatory requirements, and do not consider and are not typically concerned about whether 510(k) approvals are needed when sourcing ISO repair services for hospital-owned instruments.

VI. HOSPITALS HAVE A STRONG PREFERENCE FOR PURCHASING SERVICES FROM GPO-APPROVED VENDORS

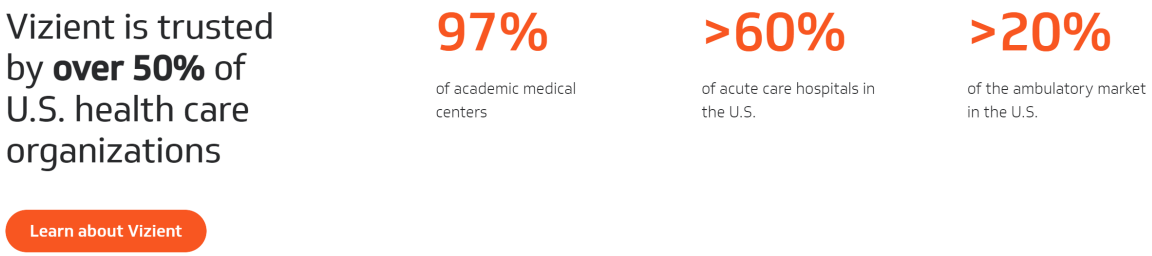
40. A GPO is a group purchasing organization that provides substantial services and benefits to its health care members. For example, a hospital chooses a GPO to act on its behalf in contracting, price negotiations, and vendor credentialing. GPOs contract with service providers for virtually all aspects of hospital operations – including ISO repair services – on behalf of their members. GPOs have thousands of members and aggregate those members' purchasing power to negotiate advantageous pricing and terms.

41. The administrative burden of negotiating and creating a contract with a vendor is significant. Hospitals prefer to access contracts and pricing that have been established by the GPO, rather than self-contracting and negotiating with individual vendors. The GPOs provide the contract start and end date, negotiated pricing, price protection, guarantees and a competitive bidding process.

42. GPOs have lists of requirements to which a vendor/manufacturer must commit and demonstrate its adherence. These requirements include compliance with FDA and other regulations, established operational and quality standards, operational history, and size and scope of organization. The contracts require that the vendor/manufacturer will comply with all local, state and federal statutes, rules, and regulations. The vendor/manufacturer will also comply with requirements of accrediting organizations.

43. I have worked with and for Vizient (one of the largest and most trusted GPOs in the industry) and its predecessor entities for well over a decade. From this, I have deep personal experience with Vizient's operations and business practices, as well as the manner in which healthcare organizations work with Vizient.

44. Vizient is a combination of three Group Purchasing Organizations – Med Assets, University Health Consortium, and VHA/Novation – that was formed in 2016. Vizient members include academic health centers, hospitals of varying sizes and location, and ambulatory care centers. Vizient acquired a smaller GPO called Intalere in 2021, expanding Vizient's membership. Whether measured by number of hospital members, percentage of health care spend, or other measures of operations and reach, Vizient presently represents 60% or more of healthcare market for acute care providers, many of which are the type of healthcare facilities that typically have da Vinci systems:[7]



45. Vizient offers not only contracted pricing for products and services, but it also has a portfolio of services to support cost containment, savings, and revenue enhancement. With respect to instrument service and repair, to my knowledge Vizient has three approved instrument service repair vendors: SIS, Steris, and Agility.

46. Prior to preparation of this Report and in preparing this Report, I have reviewed certain agreements between Vizient and SIS. I've reviewed such agreements many times from a variety of perspectives, including representing hospitals, as a consultant working through Vizient, and as an independent contractor. The agreements contain industry-standard terms and conditions

[7] www.vizient.com

as well as qualifications of the vendor to meet the expectations and requirements of the members/hospitals.

47. SIS has a general "Supplier Services Agreement" with Vizient.[8] Such an agreement contains verbiage that covers services provided, liability, failure to supply, sales reporting, compliance with law, government program participation, negligence, vendor credentialing, and service description and pricing/discounts.

48. SIS also has specific agreements with Vizient for EndoWrist "repair"[9] and EndoWrist "recovery."[10] I understand that the "repair" agreement is for a reset of the EndoWrist use counter, and provides SIS the ability to offer that service to all Vizient hospitals. Similarly, I understand that the "recovery" agreement is to perform a check of used EndoWrists for remaining lives, and provides SIS the ability to offer that service to all Vizient hospitals. To my knowledge, SIS was and is to this day the only Vizient-approved provider of EndoWrist repair services.

49. The contracting process for a hospital to individually work with an ISO is cumbersome, detailed, and time consuming. Utilizing the established contracts thru a GPO like Vizient eliminates the need for local contracting and monitoring of vendor compliance with required regulations.

50. GPOs like Vizient are paid a percentage of sales by the manufacturers/vendors who offer their devices and services through the GPO. Thus, GPOs and GPO employees are expected to connect hospitals with GPO service providers such as SIS. Some employees of the GPOs are incentivized by bonus pay based on GPO performance.

[8] SIS107399
[9] SIS047433
[10] SIS045231

51. In fact, Vizient has dozens of employees and consultants who interact with Vizient's member hospitals on a daily basis. These Vizient employees and representatives operate as a de facto salesforce for approved providers such as SIS. Particularly for high-demand service such as I understand SIS's EndoWrist repair service to be,[11] Vizient employees and representatives can and do drive adoption of the service by hospitals.

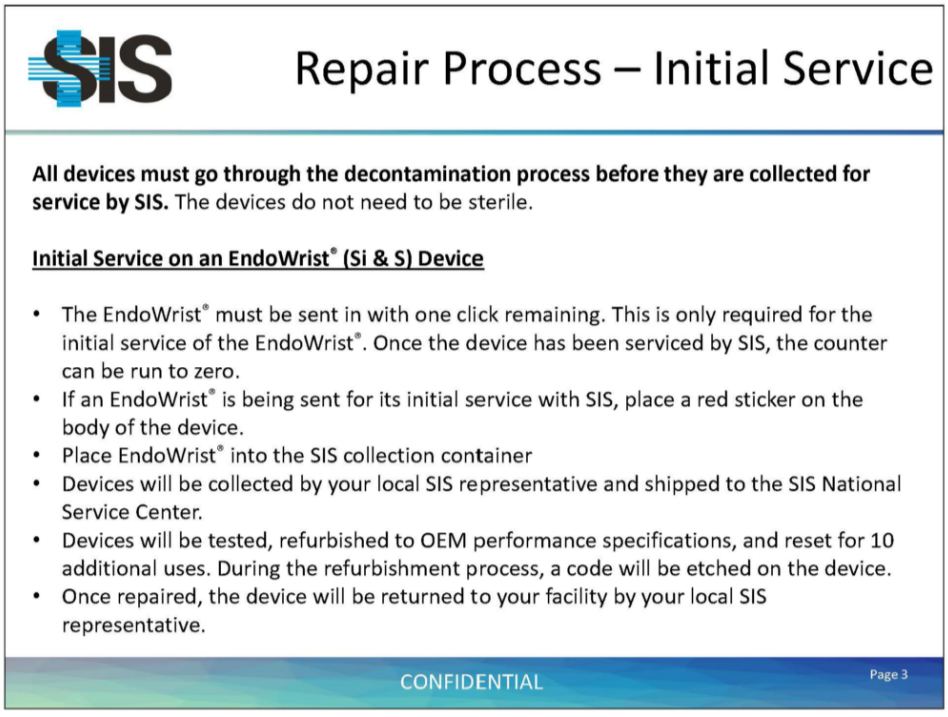
52. GPOs like Vizient have national and regional meetings for their members providing education and networking opportunities, a number of which I have attended. The vendors/manufacturers are often invited to demonstrate their products/services to the members. The educational forums allow for direct contact between senior leaders of the GPO and the hospitals. This time also allows for conversations between the vendors and hospital attendees followed by a time to meet at the hospital to further discuss how the vendors' products/services can be beneficial to the hospitals.

53. I understand that SIS provided such a presentation of its EndoWrist services to numerous of Vizient's regional sales and consultants who have access to all of the Vizient members by which they would sell this new program as a significant and easy cost savings.

54. I understand the image below is an example of a SIS presentation co-branded with Vizient:[12]

[11] Conversation with Keith Johnson; Deposition of Keith Johnson at 50:12-52:24; 30(b)(6) Deposition of Keith Johnson at 44:7-45:22.
[12] SIS106493

55. Among other things, the presentation provides an overview of the EndoWrist instrument collection and repair process offered by SIS:[13]



[13] SIS106493, at 495

56. Hospital staff would recognize this program as being simple to implement, since it merely requires decontamination of the instrument and placing it in a collection container. Given the ease of this collection process and what I understand to be the substantial per-instrument cost savings of 40% or more,[14] this collection process would likely be at the high end of general industry collection rates for instrument repairs, which in my experience would be approximately 75%.

57. In my experience with Vizient and other GPOs, where an ISO repair service provides substantial cost savings such as those offered by SIS's EndoWrist program, the combined efforts of the GPO and ISO providing such service would yield an overall conversion rate within the GPO member hospitals that I would anticipate to be about of 30% by the end of the first year, 70% by the end of the second year after the service is introduced, and 70%-80% thereafter. Examples of repair services where I have seen similar penetration rates within a GPO include electrophysiology diagnostic catheters, cables, endo shears, trocars, and laparoscopic instruments. Based on the substantial demand and combined reach of SIS and Vizient,[15] SIS could have obtained similar penetration rates within Vizient for its EndoWrist repair services, had those services not been shut down by Intuitive.

58. Hospitals access their GPOs for many reasons including new product vetting and introductions, cost savings, and contractual language. The EndoWrist repair service offered by SIS is a prime example of a service that would have offered, and today still would offer, substantial savings for every hospital having a da Vinci system and would achieve high collection and penetration rates for the GPO-approved supplier, SIS.

[14] 30(b)(6) Deposition of Keith Johnson at 95:13-18
[15] Conversation with Keith Johnson; Deposition of Keith Johnson at 50:12-52:24; 30(b)(6) Deposition of Keith Johnson at 44:7-45:22.

Dated: December 2, 2022

Jean Sargent
Jean Sargent

ATTACHMENT 1

List of Publications and Speaking Engagements

ARTICLES/WRITING

2021	Censis IDU, Impacts and Reality for Hospital's Central Service and Perioperative Loop
November 2020	*Healthcare Purchasing News* "Endoscope Care" contributor
June 2020	*Healthcare Purchasing News* "Supply Data Standards" contributor
May 2020	*Healthcare Purchasing News* "COVID-19: How is Your SPD Quaranteam Faring Amidst the Pandemic?
2019-2020	AHRMM Policy and Procedure Manual – re-write
2019	IAHCSMM Central Service Management Manual 2nd Ed., Writer
November 2019	*Healthcare Purchasing News* "Instructions for Use: what should providers do to influence the format and content"
May 2019	*Healthcare Purchasing News* "Instructions for Use: Necessary but complicated"
February 2019	AORN San Diego: "UDI Implementation for Patient Safety"
March/April 2019	IAHCSMM AORN Steam Line: "Assessing Instrument Repairs through Teamwork, Quality Measures and Metrics"
November 2018	*Healthcare Purchasing News "*Sterile Processing succeeds with standards, team efforts"
May 2018	*Healthcare Purchasing News* "Where is central service now? And why? Reflections on how career progression kept pace with the profession"
2014-2016	IAHCSMM Central Service Technical Manual 8th Ed., Writer and Reviewer
2008 – 2009	IAHCSMM Central Service Management Manual 1st Ed., Writer and Reviewer
2007 – 2010	AHRMM Healthcare Supply Chain Management, Lead, Writer and Reviewer
July 2011	*AORN Connections* - "Tracking Patient Safety"
2010	*Executive Insight Volume 1-"*GLN Sunrise is on the Horizon"
February 2010	*OR Today,* "Why GS1 Standards are Crucial to US Healthcare"
February 2010	*Healthcare Purchasing News IAHCSMM Viewpoint "*GS1 Standards Will Transform the US Healthcare Supply Chain and Improve Patient Care"
2009	*OR Today,* 'FDA Supply Tracking Standards on the Horizon: Are You Ready?"
April 2009	*Materials Management in Healthcare* "Vendor Tracking Ensures Security and Effective Cost Control Measures"
September 2008	*Materials Management in Healthcare* "Materials Management Actions Have Major Impact on Organizations"
January-December 2007	*Materials Management in Healthcare* monthly AHRMM News (as president of AHRMM)
November 2007	*Repertoire* "Materials Managers Set Course for Future"
January 2008	*HFMA Supply Chain Solutions* "What Executives Need to Know About Their Materials Management Department"
2007	IAHCSMM Central Service Technical Manual 7th Ed., Writer and Reviewer
2005	AHRMM – Self Assessment Exam Writer and Reviewer
2004	"Relationship Between the OR and CS", AORN Kimberly Clark

SPEAKING ENGAGEMENTS

August 2021	"How Will Genomics Change the Supply Chain?" AHRMM Annual COnference
September 2020	"Evaluating the Efficacy and Use of Disinfectant Products in High Touch Areas" Speaker and Moderator, IP Directors Virtual Summit
June 2020	"Supply Chain 101 and COVID-19" Healthmark Webinar
October 2019	"Mergers and Acquisitions: Before, During and After" FLARHMM Conference
July 2019	Moderator of Learning UDI Community (LUC) track AHRMM Annual Conference
May 2019	"UDI Panel Discussion" IAHCSMM
April 2019	"UDI Panel Discussion – follow up" AORN
August 2018	"Education – why it is important your staff understands their role within the organization" AHRMM Annual Conference
April 2018	"Clinical, Supply and Patient Safety Benefits of the Unique Device Identifier (UDI)
AORN	
November 2017	"Current Trends in Healthcare Supply Chain from a Supply Chain Executive Perspective" Market Insights, Supply Chain Forum Panel
August 2017	"The UDI and the OR" OR Today Conference
May 2017	"Hospital Facility Security – Who is in your hospital and do you know why they are there?" FLAHRMM Conference
May 2017	"Central Service's Role in the Unique Device Identifier (UDI) Regulation" IAHCSMM Annual Conference
May 2015	"Things You Need to Know as a First Time Supervisor" IAHCSMM Annual
Conference	
May 2014	"Key Functions of a Hospital" IAHCSMM
July 2013	"Leadership Skills Necessary for Success" AHRMM
July 2013	"Purchased Services, Contracting and Negotiations" AHRMM Annual Conference
December 2011	"Recall Management" FDA UDI Meeting
October 2011	"Recalls, Unique Device Identifier, Case Study: Implementation of Standards within a Hospital" GS1 Global Meeting Amsterdam
2008 - 2014	"Improving Patient Safety and Supply chain Efficiency with Data Standards: The Basics of GS1 Healthcare Standards in Healthcare" Multiple webinars
December 2010	"Exploring Potential Disconnects Between Manufacturers and Hospitals in the Recall Process" with Dennis Black, BD at FDA Unique Device Identifier Conference
October 2010	"The Basics of GS1 Standards" CAHPMM
August 2010	"Implementation of RFID System" AHRMM
October 2009	"Getting to Know the Standards" HIGPA
May 2009	"Barcoding and Patient Safety, Industry Standards", IAHCSMM
May 2009	"How to Plan Staff In-services" IAHCSMM
January 2009	"Supply Chain- Cost Savings Strategies" HFMA Region 11 Symposium, with Vicki Smith-Daniels, Professor Supply Chain, Arizona State University
November 2008-2015	"Improving Patient Safety and Supply Chain Efficiency with Data Standards - *The Basics of GS1 Standards in Healthcare"* Presenter, GS1 Healthcare US Webinar (multiple occasions)
Fall 2008	"Unique Supply Chain Issues and Perspectives" SMI Fall Meeting 2008 with Sergio Melgar, CFO and Dr. Richard Lofgren Chief Clinical Officer, UK Healthcare
October 2008	"GS1 Healthcare US Standards – What You Need to Know" UHC Supply Chain and Clinical Resources Council Meeting
October 2008	"GS1 Healthcare US Standards – What You Need to Know" Owens and Minor (O&M) Regional Meeting
September 2008	"Introduction to GS1 Healthcare US and Standards", IHPMMA September 2008
2008	"An Examination of the 2008 National Executive Survey on Supply Chain
Management",	

	Co-presenter with Jamie Kowalski, VP Business Development, O&M, AHA/Health Forum Leadership Summit
July 2008	"When Generations Collide" AHRMM Annual Conference
July 2008	0309"RFID Primer for Materials Managers" AHRMM Annual Conference
May 2008	"Bridging the Generation Gap", IAHCSMM Annual Conference
July 2007	"The Importance of AHRMM ", AHA Leadership Summit AHA Board Meeting
July 2006	"Selecting, Implementing and Maintaining a Point of Use System" AHRMM Annual Conference
March 2006	"Supply Chain Management, Supplies and Beyond", CCSA Conference
2006	"Selecting, Implementing and Maintaining a Point of Use System" AHRMM Technology Conference
	"Utilizing Technology to Implement Cost Effective/Efficient Supply Chain Solutions"
2004	AHRMM Conference
2004	"Inventory Distribution Management" WSHMMA Annual Conference
September 2003	"Disaster Planning", West Coast VHA Conference
March 2004	"Human Resources", CCSA
March 2003	"Basic Time Management and Supervision" "Employee Discipline and Union Interaction" CCSA
2003	"Value Analysis Panel Discussion" WSHMMA Annual Meeting
2002 Fall Meeting	"Conflict Management", "Orientation and Training" IAHCSMM
July 2002	"Managing Conflict", CCSA
March 2002	"Financial Management", CCSA Management Seminar
2001 – 2002	"Distribution", "FDA Reprocessing Regulations", CCSA Traveling Technician Seminars: Van Nuys, Fullerton, San Diego, Fresno, San Francisco, CA,
August 2002	"Central Services, Part I and II", AHRMM
November 2001	"FDA Reprocessing Regulations", CAHPMM
2001	"Central Service 101", AHRMM Annual Meeting
March 2001	"FDA Reprocessing Regulations", Southern California IAHCSMM
2000	"Central Service 101", CAHPMM Annual Meeting
May 2000	"Facility Planning", So Cal IAHCSMM
1999	"Central Service, Where Have We Been, Where Are We Going" AHRMM Annual Meeting
1998 Fall Meeting	"Year 2000 Issues, How Does This Affect Central Service" IAHCSMM

LEADERSHIP ROLES/RECOGNITION/AWARDS

2003-present	CAHPMM Education Chair
2015-2020	AHRMM Fellowship Committee Chair and Member
2014-2019	AHRMM Learning UDI Committee Lead and Member
2010-2012	GS1 Healthcare Leadership Team
2010	AHRMM George R. Gossett Leadership Award Winner
2009 – 2014	Bellwether League Board of Directors - appointed
2008-2015	GS1US Healthcare Leadership Team
2008	SMI Team Participation Recognition
2004-2008	AHRMM Board Member
2000-2006	CCSA Board President and Member
2000-2004	IAHCSMM Professional Development Resource Committee (PDRC) Chair
1999-2004	AHRMM Education Committee Member
1998-2002	CAHPMM President
1998-1999	IAHCSMM Fellowship Chair
1997	IAHCSMM Past President's Award

ATTACHMENT 2

List Of Materials Cited

The following materials were used in forming my opinions:

1. Intuitive-00000501-639
2. Intuitive-00002201-501
3. Intuitive-00096563-964
4. Intuitive-00279588-888
5. Intuitive-00284844-945
6. Intuitive-00654768
7. Intuitive-00670595-716
8. Intuitive-00676719-840
9. Intuitive-01163789-890
10. SIS000202-04
11. SIS045231-32
12. SIS047433-35
13. SIS106493-98
14. SIS107399-442
15. SIS117733-49
16. SIS346267
17. SIS357819-23
18. SIS357824-37
19. da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, PN 554324-01 Rev. B
20. Discussion with Keith Johnson, Executive Vice President, Sales and Clinical Programs at SIS
21. Deposition of Keith Johnson dated October 27, 2022
22. 30(b)(6) Deposition of Keith Johnson dated October 27, 2022